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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------|-------------|----------------------|---------------------|------------------|
| 10/598,789 | 09/12/2006 | Hiroshi Sugiyama | Q96589 | 1416 |
| 23373 | 7590 | 08/07/2009 | EXAMINER | |
| SUGHRUE MION, PLLC | | | CHU, YONG LIANG | |
| 2100 PENNSYLVANIA AVENUE, N.W. | | | | |
| SUITE 800 | | | ART UNIT | PAPER NUMBER |
| WASHINGTON, DC 20037 | | | 1626 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 08/07/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/598,789 | SUGIYAMA ET AL. | |
| | Examiner | Art Unit | |
| | YONG CHU | 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 July 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 and 21-25 is/are rejected.
- 7) Claim(s) 1-17 and 21-25 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 1-2, 4-13, and 21 have been amended by the Amendment on 11/17/2008.

Claims 18-20 were cancelled. Claims 22-25 are new by the Amendment. Therefore, claims 1-17 and 21-25 are pending in this application.

Response to Amendments

The Amendments by Applicants' representative Sunhee Lee dated on 11/17/2008, 01/15/2009, and 07/10/2009 have been entered. The sequence listing on 07/10/2009 has been entered.

Response to Arguments/Amendment

Specification

Applicants' amendment of Specification on 01/15/2009 has been entered.

Claim rejection under 35 U.S.C. §112, 1st paragraph

Applicants have cancelled the rejected claims 18-20. The rejection of claims 18-20 is moot. However, the rejection over rejected claim 21 is maintained, because the term "an oncogene" are not described in such way to show one ordinary skill in the art for possession of the invention, because the term "oncogene" is not fully described as articulated in the previous Office action at page 5. Therefore, the rejection of claim 21 is maintained.

Claim rejection under 35 U.S.C. §103(a)

Applicants' amendment by removing "one constitutional unit" of claim 1 overcomes the art rejection.

Claim objection

Since the Amendment has overcome the art rejection, and search and examination are expanded to part of the previously non-elected subject matter. The objection of the claims for containing non-elected subject matter is moot.

Since the amendment has overcome the cited art rejection, the Examiner has expanded the search to part of the previously non-elected subject matter, and new prior art anticipates the expanded scope of subject matter as disclosed follow:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

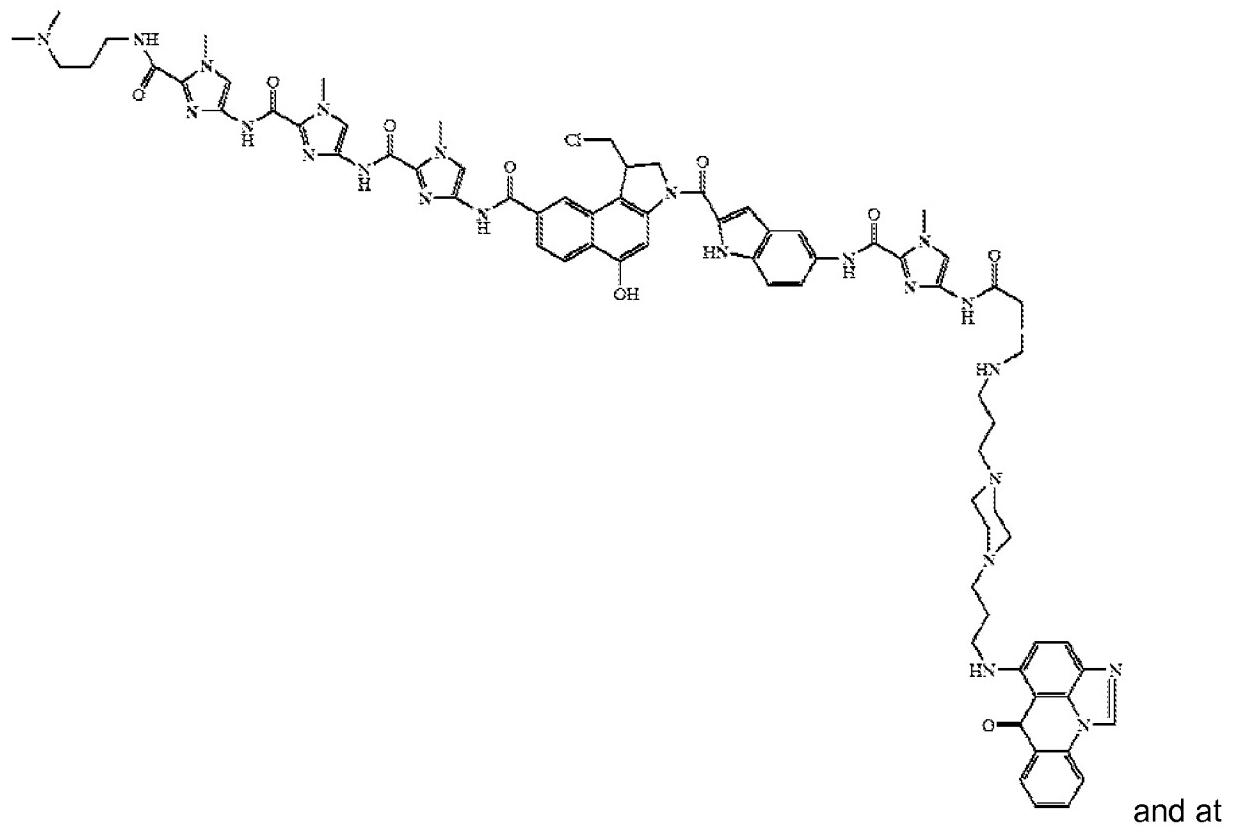
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

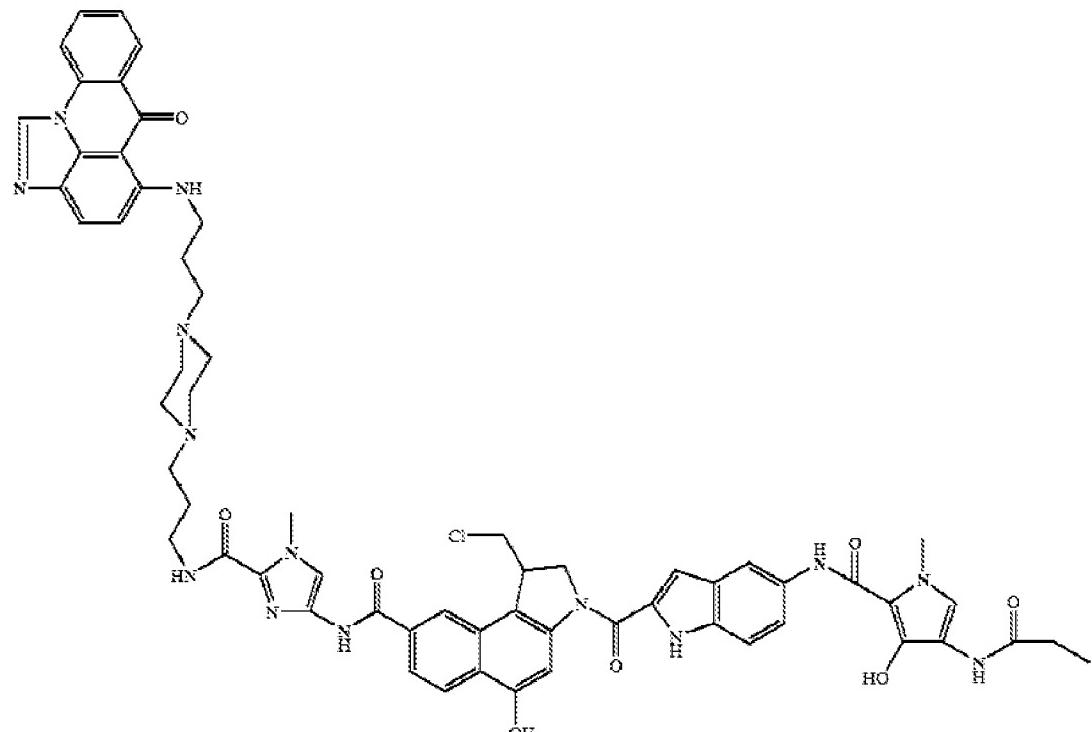
Claims 1-2, 14-15, 17, 21-23, and 25 are rejected under 35 U.S.C. 102 (b) as being anticipated by Szekely et al., WO2003072058 ("the '058 publication", corresponding U.S. Publication US20050096261).

The '058 publication disclosed series of compounds as DNA-binding polyamide drug candidate for treating cancer with specific examples at paragraph [0062] of formula (VI)

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paragraph [0068] of formula (VII)



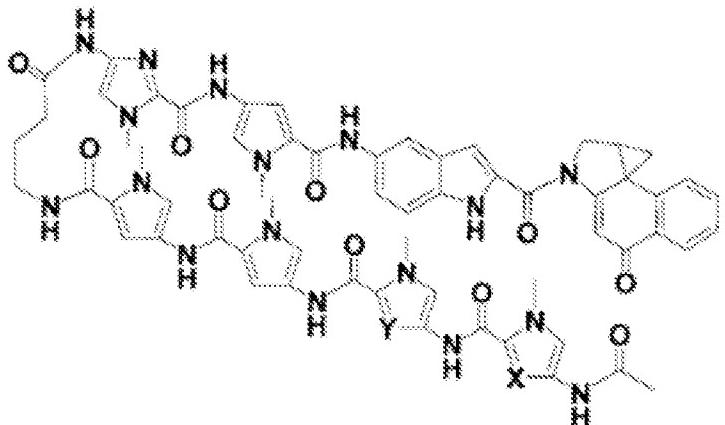
. The

compounds anticipate the instantly elected and examined scope of invention.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 5, 8, 14-17, and 21-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Sasaki et al. *Nucleic Acids Symposium Series, No. 48, pp. 205-206*, published in Nov. 2004.

Sasaki et al. disclosed series of DNA-alkylating polyamide compounds, which can be used for treating cancer with specific examples of the formulae:



- | | |
|-------------------|--------------------|
| 1 $X = N, Y = N$ | 3 $X = N, Y = CH$ |
| 2 $X = CH, Y = N$ | 4 $X = CH, Y = CH$ |

The compounds anticipate the instantly elected and examined scope of invention. This rejection under 35 U.S.C. 102(a) might be overcome by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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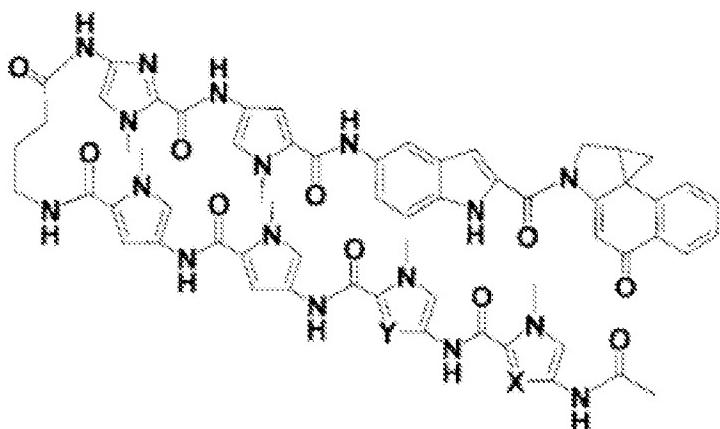
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17, and 21-25 are rejected under 35 U.S.C. 103 (a) as unpatentable over the Sasaki teaching in view of the '058 publication.

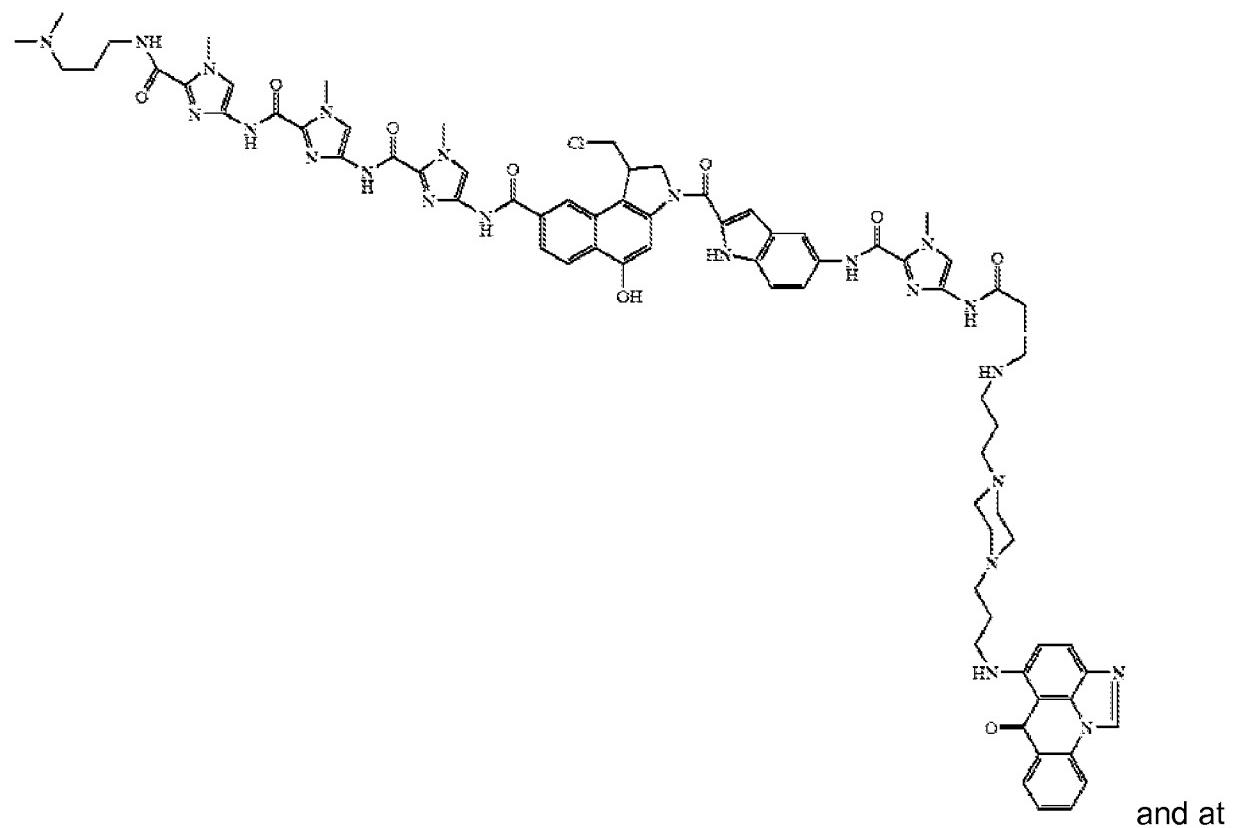
Determination of the scope and content of the prior art (MPEP §2141.01)

Sasaki et al. disclosed series of DNA-alkylating polyamide compounds, which can be used for treating cancer with specific examples of the formulae:

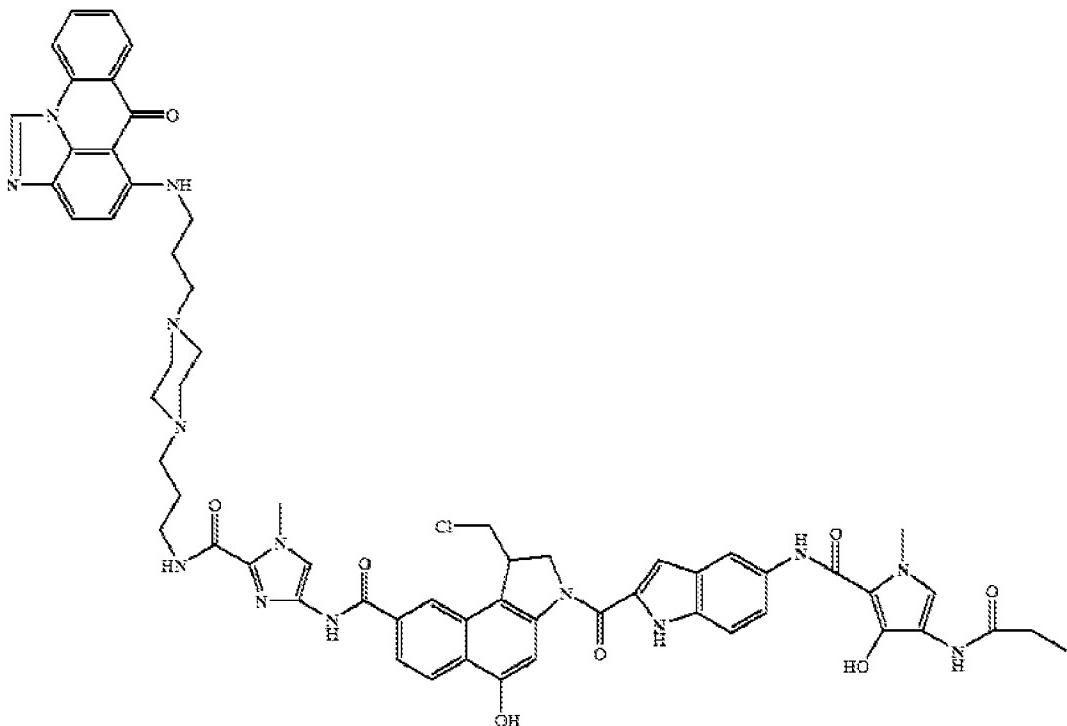


The '058 publication disclosed series of compounds as DNA-binding polyamide drug candidate for treating cancer with specific examples at paragraph [0062] of formula

(VI)



paragraph [0068] of formula (VII)



Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the Sasaki teaching and the instantly claimed compound is that the linker of **X** can be $-(CH_2)_n-$ wherein **n** is 0-10 for the instant application, while the prior art teaching specifically **n** as 3. The difference can also be the difference the order of the constitutional unit of **X**.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

However, the instantly claimed compounds would have been obvious over the prior art teachings as a whole. It is because the prior art teaches DNA-alkylating polyamide compounds, which are the same utility as the instantly claimed compounds. The repeating constitutional units and hair-pin DNA-binding structure are all taught by the prior art references. The motivation to make the claimed compounds derives from

the expectation that knowing properties of one member of series compounds would in general know what to expect in adjacent members as DNA-alkylating for treating cancer. Therefore, the instant claimed compounds would have been suggested to one skilled in the art. This rejection under 35 U.S.C. 103(a) might be overcome by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another" (e.g. the other two authors do not participate the invention).

Claim Objections

New claims 22-23 are objected to because of the following informalities: The formulae in claims 22 and 23 are not clear. Appropriate correction is required.

Conclusions

- No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu, Ph.D., whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M^cKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Yong Chu
Patent Examiner
Art Unit 1626